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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/553,523 | 10/14/2005 | Yoshiharu Uehata | 10921.362USWO | 1562 |

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| EXAMINER | |
|---|---|
| WAQAS, MUHAMMAD | |
| ART UNIT | PAPER NUMBER |
| 4153 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

CT

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/553,523 | UEHATA ET AL. | |
| | Examiner | Art Unit | |
| | Muhammad Waqas | 4153 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe et al. (US Patent No.7, 244,266), in view of Searle et al. (US Patent Publication No. 2002/0087180A1).

Garthe discloses an invention comprises of movable lancet holder (column 3, line 41) that holds the lancet (figure 4) and move in the predetermine path to stick into the object and cause puncture (column 3, lines 42-44).

Garthe fails to disclose a lancet holder having two relative moving members. However, Searle discloses an invention comprised of relatively moving members, which holds the lancet (abstract, fig1). These two relatively moving members are cap and base (abstract, line 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's invention to that of lancet loading and lancet holder design as taught by Searle so as to enhance better holding of the lancet and to improve its functionality.

Concerning claims 19 and 20, Searle discloses an invention comprised of two relative moving members. The two members are engaged together as by pushing one member causes second member to move in the lacing direction (paragraph [008]). The pushing member (figure 7, (20)) includes a working portion (figure 7, (12)) that moves and engages with second member (figure 8, (16)). It further would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's invention and add pushing member as taught by Searle so as to obtain better functionality of the lancet apparatus.

3. Claims 2, 3, 4, 8, 9, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe, in view of Searle as applied to claim 1 above and further in view of Kageyama et al. (US Patent No. 6,039,485).

Garthe and Searle combination (hereinafter combination 1) fails to disclose a lancet holding mechanism that comprises two relative moving members and distance between these members changes as they move, which results in holding the lancet. However, Kageyama discloses an invention composed of relative moving members (figure 10 and12 (34), (26)) that apply pressing force to holds a lead in between. The two members mentioned are tip chunk and delivery chunk (column 1, lines 36-45). Although this invention is used to hold the lead, however this holding mechanism of Kageyama's invention is capable of holding a lancet. The holder applies greater pressing force due to the movement of relative moving members. The holding space between holding members decreases as they moves relative to each other, which results in pressing and holding, as it said, "The size of the gap "d" further decreases to

reliably tighten the lead when the tip chuck 34 moves backward to its rear-most position, into the tip fitting 12" (column 10, lines 20-22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's combination 1 and use the holding mechanism as taught by Kageyama so as to enhance firm holding capability of lancet holder.

Concerning claims 16 and 17, Kageyama discloses an invention comprises of two movable members. The gap between these members changes as they move relative to each other (column 10, lines 20-24). The distance between these two members decreases when one member move in retreating direction with respect to other member (column 10, line 20) and vice versa. It further would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's combination 1 and add lancet-holding mechanism as taught by Kageyama so as to obtain efficient loading and unloading of the lancet.

4. Claims 5, 6, 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe's, Searle's and Kageyama's combination (hereinafter combination 2) of references as applied in the rejection of claim 2, and further in view of Kiehne et al. (US Patent No 6,629,985). Garthe's combination 2 fails to disclose a lancet holding mechanism that comprises engaging portions. However, Kiehne discloses an invention having first engaging portion and a second engaging portion (figure 1, 10 and 11) that results in a fixing means. The engaging members contain recess and projection to be fitted into a recess (column 4, lines 11-14 and Fig 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's combination

2 to include engaging portions with projection and recess for fixing means as taught by Kiene so as to make the lancet holder compact with better holding capability.

5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe's combination 3 of references as applied in the rejection of claim 9, in further view of Okumura et al. (US Patent No. 6,226,873). Garthe's combination 3 fails to disclose that lancet holding mechanism contains cutaway portions. However, Okumura discloses an invention that comprised of movable portions, which includes cutaway (figure 1, (1b)). The working portion fits into the cutaway (figure 1 and column 1, lines 52-62). Therefore, It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's combination 3 and add cutaway portion as taught by Okumura so as to have system with better locking capability.

Concerning claim 11, Searle discloses an invention, which contains first cutaway portion into which working portion (figure 7, (26), (46)) is fitted in fixing the lancet (figure7) and second cutaway portion into which working portion is fitted in discharging the lancet (figure 9). It further would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's combination 3 and add cutaway portion as taught by Searle so as to have better control in locking the lancet.

7. Claims 12,13,14,and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe's combination 4 of references as applied in the rejection of claim 11, in further view of Ritson et al. (US Patent No. 5,041,088). Garthe's combination 4 fails to disclose that the change in the gap of lancet holding mechanism is a stepped change. However, Ritson discloses a lancing apparatus that contains a

stepped portion for change in gap (column 4, lines 36-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's combination 4 and add a step portion for change in the diameter of holding mechanism as taught by Ritson so as to have rapid fixation of the lancet.

***Double Patenting***

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of US Patent Publication No. 2007/0055297A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims discloses lancet holder that holds the lancet and move in certain direction to make puncture, both claims includes first and second moving members that moves relative to each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Muhammad Waqas whose telephone number is (571)270-3817. The examiner can normally be reached on Mon-Thurs. 8:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MW (MW)
10/11/07

GARY JACKSON
SUPERVISORY PATENT EXAMINER